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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,392	09/05/2006	Markus Stoffel	11937/US/2	3339
23869	7590	01/12/2009		
HOFFMANN & BARON, LLP 6900 JERICO TURNPIKE SYOSSET, NY 11791			EXAMINER QIAN, CELINE X	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 01/12/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/551,392		STOFFEL ET AL.	
	Examiner		Art Unit	
	CELINE X. QIAN		1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Claims 1-50 are pending in the application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-13, drawn to a method for identifying an agent that increases Foxa-2 expression comprising contacting a plurality of cells that contain a Foxa-2 promoter operably linked to a coding sequence for Foxa-2 or a reporter gene with a candidate agent; assaying for expression of Foxa-2 or the reporter expression in the presence and absence of the candidate agent, whereby increase in Foxa-2 or reporter expression in the presence of the candidate agent is indicative of the identification of an agent that increases Foxa-2 expression.

Group II, claim(s) 14, drawn to a composition comprises an agent that increases Foxa-2 expression.

Group III, claims 15-27, drawn to a method for identifying an agent that increases Fxr expression comprising contacting a plurality of cells that contain a Fxr promoter operably linked to a coding sequence for Fxr or a reporter gene with a candidate agent; assaying for expression of Fxr or the reporter expression in the presence and absence of the candidate agent, whereby increase in Fxr or reporter expression in the presence of the candidate agent is indicative of the identification of an agent that increases Fxr expression.

Group IV, claim 28, drawn to a composition comprises an agent that increases Fxr expression.

Group V, claims 29-31, drawn to a method of identifying an agent that activates Fxr comprising contacting a plurality of cells that contain Fxr with a candidate agent; assaying for activation of Fxr in the presence and absence of the candidate agent; and comparing activation of Fxr in the presence and absence of the candidate agent, wherein an increase in activation in the presence of the agent is indicative of the identification of an agent that activates Fxr.

Group VI, claim 32, drawn to a composition comprising an agent that activates Fxr.

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Group VII, claims 33-35 and 38, drawn to a method of inhibiting adipogenesis or treating obesity/metabolic syndrome or type 2 diabetes comprising contacting a cell with an agent that increases mRNA or protein of Foxa-2.

Group VIII, claims 33-38, drawn to a method of inhibiting adipogenesis or treating obesity/metabolic syndrome or type 2 diabetes comprising contacting a cell with an agent that increases levels of Fxr mRNA or protein.

Group IX, claims 33-35 and 38, drawn to a method of inhibiting adipogenesis or treating obesity/metabolic syndrome or type 2 diabetes comprising contacting a cell with an agent that activates Fxr.

Group X, claims 39-42, drawn to a method of identifying an agent that inhibits the phosphorylation of Foxa-2 comprising combining a candidate agent with a polypeptide having Akt kinase activity and a substrate comprising phosphorylation domain of Foxa-2; assaying for phosphorylation of the substrate in the presence or absence of the candidate agent, whereby a decrease in phosphorylation of the substrate in the presence of the candidate agent is indicative of the identification of an agent that inhibits phosphorylation of Foxa-2.

Group XI, claim 43, drawn to a composition comprising an agent that inhibits the phosphorylation of Foxa-2.

Group XII, claims 44-47, drawn to a method of identifying an agent that inhibits the nuclear exclusion of Foxa-2 in hepatocytes comprising contacting a plurality of hepatocytes with a candidate agent; determining the intracellular location of Foxa-2 in the presence and absence of the candidate agent; and comparing the intracellular location of Foxa-2 in the presence and absence of the candidate agent, whereby an increase in nuclear localization of Foxa-2 in the presence of the candidate agent is indicative of the identification of an agent that inhibits nuclear exclusion of Foxa-2 in hepatocytes.

Group XIII, claim 48, drawn to a composition comprising an agent that inhibits the nuclear exclusion of Foxa-2.

Group XIX, claim 49, drawn to a method of treating obesity, type 2 diabetes or hyperinsulinemia comprising administering to a subject the composition comprising an agent that inhibits the phosphorylation of Foxa-2.

Group XX, claim 50, drawn to a method of treating obesity, type 2 diabetes or hyperinsulinemia comprising administering to a subject the composition comprising an agent that inhibits the nuclear exclusion of Foxa-2.

PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as

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Groups I-XX do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The “special technical feature” of Group I is a cell comprising a Foxa-2 promoter operably linked to a reporter gene, which is shown by Guo et al. (PNAS, 2002. Vol. 99, No.6, pages 3663-3667, see page 3666, Figure 4 and legend, and 3664, 1st col., 1st paragraph, lines 1-3 and 15) to lack novelty or inventive step over the disclosed 293 cell line comprising vector that comprises Foxa-2 promoter operably linked to CAT reporter gene, and does not make a contribution over the prior art. As such, this technical feature cannot link the invention as a whole to form a single general inventive concept under PCT Rule 13.1.

Since the special technical feature of Group I does not make a contribution over prior art as shown, each of the remaining group has its own special technical feature which is not shared by other groups. Therefore, the unity of the invention does not exist between Groups I-XX.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELINE X. QIAN whose telephone number is (571)272-0777.

The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Celine X Qian /
Primary Examiner, Art Unit 1636